AMENDMENT

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir/Madam:

The applicant wishes to thank the Examiner for the extension as a result of Applicant's overlooking the rejection of claims 19-36 under 35 USC 103(a) and presents the following to complete the record.

In response to the Office Action dated July 28, 2004, directed to the above-identified U.S. patent application, please enter the herein response.

REMARKS

Claims 1-36 are present in the instant application. No claims have been indicated to be allowable. A response on Claims 1-18 under 35 USC 103(a) was filed on May 3, 2004.

Claims Objections:

35 USC 103 (a)

Claims 19-36 stand rejected under 35 USC 103 (a) as unpatentable over Kodera et al., 6,455,273 B1, Kurtz et al., 5,639,788 and Daravingas et al., 6,235,320 in view of Cherukuri et al., 5,013,716 and Blase et al., 5,409,907.

Office Action Item 2.

Claims 19-36 stand rejected under 35 USC 103 (a) as unpatentable over Kodera et al., 6,455,273 B1, Kurtz et al., 5,639,788 and Daravingas et al., 6,235,320 in view of Cherukuri et al., 5,013,716 and Blase et al., 5,409,907.

Kodera et al., Kurtz et al., and Daravingas et al., disclose that amino acids, protein

hydrolysates, peptides and polypeptides have a bitter taste as stated by Applicant (page 2, second paragraph). Cherukuri et al. disclose taste masked pharmaceutical compositions containing analgesics, antitussives, antihistamines, decongestants, expectorants, or NSAIDS. Blase et al., discloses aqueous pharmaceutical compositions containing an active agent and a taste masking composition containing a sweetening agent such as sucralose.

It was noted in the specification of the present application that Cherukuri et al. (Issued May 7, 1991)did not mention the use of sucralose with proteins, amino acids, amino acid analogs or protein hydrolysates (p. 4) among the broadly claimed "medicament drugs". In fact, Cherukuri et al. recognized that the invention would not be useful in masking the unpalatable flavor of proteins, amino acids, amino acid analogs or protein hydrolysates by noting that the preferred embodiment contains materials having an unpalatable flavor at a level of "0.0001% to about 5.0%" and then combines these with the "intense sweetening agent present in an amount from about 0.001% to 5.0%" (Col 4, lines 4-21) The protein hydrolysate of Kodera et al., were to be incorporated into "foodstuffs, infant formulas, medicinal diets, ..." (Col 2, lines 15-19). Such foodstuffs normally have amino acid or protein concentrations of higher than 5% (as an example 17% in Vivonex label provided at interview, a Novartis Nutrition Corp. product).

A later patent, Blase et al. (filed December 16, 1993), in reviewing the status of the art states, "a common problem associated with liquid pharmaceutical dosage forms is the often disagreeable taste of a drug that may manifest itself when the drug is in a liquid dosage form. Sometimes, the taste of the drug in the dosage form may be overpowered by adding sweeteners or flavoring agents to the liquid dosage. These agents mask the bitter or unpleasant taste of drugs. **However, these agents are not totally effective in concealing the unpalatable taste of pharmaceuticals.**"(Col 1, lines 41-49). Thus, it is clear that at the time of this filing (after the Cherukuri et al., issue date), the ability of sweeteners alone was known **not** to be sufficient to effectively mask the unpalatable taste of pharmaceuticals, but in addition required the use of the minimal water suspensions of the invention. This taste masking effect of Blase et al., is obtained by "limiting the amount of water in our suspension ... Since, the pharmaceutical active remains in the solid (undissolved) form, the pharmaceutical is less likely to be tasted while in the mouth." (Col 2, lines 45-51)

Blase et al., in Claim 1, include some of the analgesics (specifically acetaminophen), antitussives (dextromethorphan), antihistimines (specifically chlorpheniramine), decongestants (specifically pseudoephedrine), expectorants (specifically guaifenesin), of Cherukeri et al., **thus teaching away from the present invention.** Reading Blase et al., clearly demonstrates the need for additional technology other than the sweeteners of claim 2 to mask bitter or unpleasant tastes. Blase et al., tested an analgesic, one of the broad assertions made by Cherukuri et al., where only chewing gums were tested, and **found that without limitation of water in the formulation, the taste was unsuitable** (Col. 5, line 10-12). Applicant believes that this is further proof that the results of using sufficient levels of sucralose to mask bitter tastes is unobvious in that the combination of Kodera et al., Kurtz et al., Daravingas et al., with Cherukuri et al., and Blase et al., would have **led one to believe that the method disclosed in the Applicant's invention would be a failure**.

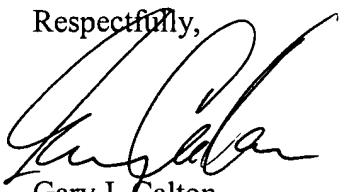
As disclosed in the present invention, the method of using sucralose as a taste masking agent is not generally applicable to amino acids as the offtaste of arginine **is not masked** by the method of adding sucralose, even in extremely high amounts.

The aforementioned Patentees have not found Applicant's unobvious and unique method use of sucralose as a taste masking agent in the aforementioned nutritionals, even when taken in combination as they in fact teach away from the instant application. Thus, **the method of using sucralose as recited in claims 18-36 is not obvious.**

Conclusion

For all the reasons given above, Applicant respectfully submits that the claimed distinctions are of patentable merit under Section 103. Accordingly, applicant submits that this application is now in full condition for allowance, which action Applicant respectfully solicits.

Respectfully,



Gary J. Calton

Applicant Pro Se

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Pursuant to 37 C.F.R. §1.8, I hereby certify that I have a reasonable basis to expect that this correspondence will be deposited with the United States Postal Service on or before the dated indicated, as Express Mail ET543656353US in an envelope addressed to Commissioner of Patents and Trademarks, P.O. Box 1450 Alexandria, VA 22313-1450

8/20/04
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